



# SAFETY DATA SHEET

Revision date 16-Jun-2025

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Meperidine Hydrochloride Injection (Hospira, Inc.)  
**Product Code(s)** PZ03106  
**Trade Name:** DEMEROL  
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as Analgesic

### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Reproductive toxicity** Category 2 - (H361d)

#### OSHA Classification

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements

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## Signal word

Warning

## Hazard statements

H361d - Suspected of damaging the unborn child

## Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P405 - Store locked up

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

## 2.3. Other hazards

### Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

## PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

## Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

## Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Meperidine Hydrochloride (CAS #: 50-13-5)	1		200-013-3	Acute Tox 3 (H301) Repr2 (H361d)	Not classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5%	No data available	No data available

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					Skin Corr. 1B :: 2%≤C<5% Skin Irrit. 2 :: 0.5%≤C<2%		
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 10%≤C<25% Skin Corr. 1B :: C≥25% Skin Irrit. 2 :: 10%≤C<25% STOT SE 3 :: C≥10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Meperidine Hydrochloride 50-13-5	162	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

This product does not contain candidate substances of very high concern at a concentration ≥0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## Additional information

+ Substance with a Union workplace exposure limit

\*\* to adjust pH

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. Non-hazardous ingredients provided for completeness. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## Section 4: FIRST AID MEASURES

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## 4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	If symptoms persist, call a physician.
Skin contact	Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

## 4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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## 4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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## **Section 5: FIRE-FIGHTING MEASURES**

### 5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.
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### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.
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Hazardous combustion products	Formation of toxic gases is possible during heating or fire.
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#### Explosion data

Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information available.

### 5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## **Section 6: ACCIDENTAL RELEASE MEASURES**

### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders	Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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### 6.3. Methods and material for containment and cleaning up

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**Methods for containment**  
**Methods for cleaning up**  
**Prevention of secondary hazards**

Prevent further leakage or spillage if safe to do so.  
Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.  
Clean contaminated objects and areas thoroughly observing environmental regulations.

## 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

**Advice on safe handling** Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

Refer to available public information for specific member state Occupational Exposure Limits.

#### **Meperidine Hydrochloride**

Pfizer OEL TWA-8 Hr: 30 µg/m<sup>3</sup>

#### **SODIUM CHLORIDE**

Latvia

TWA: 5 mg/m<sup>3</sup>;

Russia

MAC: 5 mg/m<sup>3</sup>

#### **Sodium hydroxide**

ACGIH OEL (Ceiling)

2 mg/m<sup>3</sup>

ACGIH TLV

Ceiling: 2 mg/m<sup>3</sup>

Austria

TWA-TMW: 2 mg/m<sup>3</sup>; inhalable fraction

STEL-KZGW: 4 mg/m<sup>3</sup> (8 X 5 min); inhalable fraction

Bulgaria

TWA: 2.0 mg/m<sup>3</sup>; alkaline aerosols

Czech Republic

1 mg/m<sup>3</sup>

Ceiling: 2 mg/m<sup>3</sup>

Denmark

Ceiling: 2 mg/m<sup>3</sup>;

Estonia

TWA: 1 mg/m<sup>3</sup>;

STEL: 2 mg/m<sup>3</sup>;

Finland

Ceiling: 2 mg/m<sup>3</sup>;

France

2 mg/m<sup>3</sup>

Hungary

TWA-AK: 1 mg/m<sup>3</sup>;

STEL-CK: 2 mg/m<sup>3</sup>;

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Ireland	STEL: 2 mg/m <sup>3</sup> ;
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	TWA: 0.5 mg/m <sup>3</sup> ;
Poland	TWA-NDS: 0.5 mg/m <sup>3</sup> ;
	STEL-NDSch: 1 mg/m <sup>3</sup> ;
Romania	TWA: 1 mg/m <sup>3</sup> ;
	STEL: 3 mg/m <sup>3</sup> ;
Slovakia	TWA: 2 mg/m <sup>3</sup> ;
Spain	STEL (VLA-EC): 2 mg/m <sup>3</sup> ;
Switzerland	TWA-MAK: 2 mg/m <sup>3</sup> ; inhalable dust
	STEL-KZGW: 2 mg/m <sup>3</sup> ; inhalable dust
OSHA PEL	TWA: 2 mg/m <sup>3</sup>
	(vacated) Ceiling: 2 mg/m <sup>3</sup>
United Kingdom	STEL: 2 mg/m <sup>3</sup> ;
<b>+ Hydrochloric Acid</b>	
ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	TWA-TMW: 5 ppm;
	TWA-TMW: 8 mg/m <sup>3</sup> ;
	STEL-KZGW: 10 ppm (8 X 5 min);
	STEL-KZGW: 15 mg/m <sup>3</sup> (8 X 5 min);
Bulgaria	TWA: 5 ppm;
	TWA: 8.0 mg/m <sup>3</sup> ;
	STEL: 10 ppm;
	STEL: 15.0 mg/m <sup>3</sup> ;
Czech Republic	8 mg/m <sup>3</sup>
	Ceiling: 15 mg/m <sup>3</sup>
Denmark	STEL: 5 ppm;
	STEL: 8 mg/m <sup>3</sup> ;
Estonia	TWA: 5 ppm;
	TWA: 8 mg/m <sup>3</sup> ;
	STEL: 10 ppm;
	STEL: 15 mg/m <sup>3</sup> ;
European Union	TWA: 5 ppm;
	TWA: 8 mg/m <sup>3</sup> ;
	STEL: 10 ppm;
	STEL: 15 mg/m <sup>3</sup> ;
Finland	STEL: 5 ppm;
	STEL: 7.6 mg/m <sup>3</sup> ;
Germany DFG	TWA-MAK: 2 ppm; I(2);
	TWA-MAK: 3.0 mg/m <sup>3</sup> ; I(2);
	Peak: 4 ppm;
	Peak: 6 mg/m <sup>3</sup> ;
Germany TRGS	TWA-AGW; 2 ppm (exposure factor 2);
	TWA-AGW; 3 mg/m <sup>3</sup> (exposure factor 2);
Hungary	TWA-AK: 8 mg/m <sup>3</sup> ;
	TWA-AK: 5 ppm;
	STEL-CK: 165 mg/m <sup>3</sup> ;
	STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m <sup>3</sup> ;
	TWA: 5 ppm;
	STEL: 10 ppm;
	STEL: 15 mg/m <sup>3</sup> ;
Italy MDLPS	TWA: 5 ppm;
	TWA: 8 mg/m <sup>3</sup> ;
	STEL: 10 ppm;
	STEL: 15 mg/m <sup>3</sup> ;
Ceiling Limit Value	2 ppm

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Latvia	3.0 mg/m <sup>3</sup> TWA: 5 ppm; TWA: 8 mg/m <sup>3</sup> ; STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m <sup>3</sup> ; STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ;
Poland	TWA-NDS: 5 mg/m <sup>3</sup> ; STEL-NDSch: 10 mg/m <sup>3</sup> ;
Romania	TWA: 5 ppm; TWA: 8 mg/m <sup>3</sup> ; STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ;
Russia	MAC: 5 mg/m <sup>3</sup>
Slovakia	TWA: 5 ppm; TWA: 8.0 mg/m <sup>3</sup> ; Ceiling: 15 mg/m <sup>3</sup> ;
Spain	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m <sup>3</sup> ; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m <sup>3</sup> ;
Switzerland	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m <sup>3</sup> ; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m <sup>3</sup> ;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm
OSHA PEL	7 mg/m <sup>3</sup> Ceiling: 5 ppm Ceiling: 7 mg/m <sup>3</sup> (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m <sup>3</sup>
United Kingdom	TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m <sup>3</sup> ; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m <sup>3</sup> ; gas and aerosol mist

## Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

## SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

## 8.2. Exposure controls

### Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep

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## Personal protective equipment

airborne contamination levels below the exposure limits listed above in this section. Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

## Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

## Hand protection

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

## Skin and body protection

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

## Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

## Thermal hazards

No information available.

## Environmental exposure controls

No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Appearance	Solution
Physical state	Liquid
Color	Colorless
Odor	No information available.
Odor threshold	No information available

Property	Values
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	3.5-6.0
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available



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Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

## 9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

### 9.2.1. Information with regard to physical hazard classes

No information available

### 9.2.2. Other safety characteristics

No information available

## Section 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

Reactivity No information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

### 10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	The information included in this section describes the potential hazards of the individual ingredients
Short term	Use of this drug is habit forming. Addiction may occur.
Long Term:	Due to its pharmacological action, exposure to this compound may produce adverse effects on fetal development.
Known Clinical Effects:	The most common adverse effects seen during clinical use of this drug include lightheadedness dizziness sedation sweating nausea vomiting constipation, constriction of the pupil (miosis) respiratory depression respiratory arrest circulatory failure symptoms of dependence/withdrawal
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.

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**Respiratory or skin sensitization** Based on available data, the classification criteria are not met.  
**STOT - single exposure** Based on available data, the classification criteria are not met.  
**STOT - repeated exposure** Based on available data, the classification criteria are not met.  
**Reproductive toxicity** Suspected of damaging the unborn child.  
**Germ cell mutagenicity** Based on available data, the classification criteria are not met.  
**Carcinogenicity** Based on available data, the classification criteria are not met.  
**Aspiration hazard** Based on available data, the classification criteria are not met.

## **Acute Toxicity: (Species, Route, End Point, Dose)**

### **Meperidine Hydrochloride**

Rat Oral LD50 170 mg/kg  
Mouse Oral LD50 178 mg/kg

### **SODIUM CHLORIDE**

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>  
Rat Oral LD 50 3 g/kg  
Mouse Oral LD 50 4 g/kg  
Rabbit Dermal LD 50 > 10 g/kg

### **Sodium hydroxide**

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Meperidine Hydrochloride	= 162 mg/kg ( Rat )	-	-
SODIUM CHLORIDE	= 3550 mg/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
+ Hydrochloric Acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h

## **Irritation / Sensitization: (Study Type, Species, Severity)**

### **SODIUM CHLORIDE**

Skin irritation Rabbit Mild  
Eye irritation Rabbit Mild

### **Sodium hydroxide**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

### **+ Hydrochloric Acid**

Skin irritation Severe  
Eye irritation Severe

## **Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

### **+ Hydrochloric Acid**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vivo* Micronucleus Rat Negative

### **Carcinogenicity**

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### **+ Hydrochloric Acid**

IARC

Group 3

## **11.2. Information on other hazards**

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## 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 11.2.2. Other information

**Other adverse effects** No information available.

## **Section 12: ECOLOGICAL INFORMATION**

**Environmental Overview:** Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated. Based on available data, the classification criteria are not met.

### 12.1. Toxicity

**No information available**

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

### 12.4. Mobility in soil

**Mobility in soil** No information available.

### 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## **Section 13: DISPOSAL CONSIDERATIONS**

### 13.1. Waste treatment methods

#### **Waste from residues/unused products**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific

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provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

**Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.**

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental Hazard(s):</b>	Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

#### Meperidine Hydrochloride

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	200-013-3

#### SODIUM CHLORIDE

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present

#### Sodium hydroxide

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5
	Schedule 6

#### + Hydrochloric Acid

<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed

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<b>TSCA</b>	Present
<b>EINECS</b>	231-595-7
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6

## National regulations

### France

#### **Occupational Illnesses (R-463-3, France)**

Chemical name	French RG number
SODIUM CHLORIDE 7647-14-5	RG 78

### Germany

#### **Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

### **TRGS 905**

Not applicable

### Switzerland

**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable

**Storage of Hazardous Material** Not applicable

**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20** Not applicable

**Major Accidents Ordinance SR 814.012** Not applicable

### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### **Authorizations and/or restrictions on use:**

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide 1310-73-2	75	-
+ Hydrochloric Acid 7647-01-0	75	-

### **Persistent Organic Pollutants**

Not applicable

### **Named dangerous substances per Seveso Directive (2012/18/EU)**

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid 7647-01-0	25	250

### **Ozone-depleting substances (ODS) Regulation (EU) 2024/590**

Not applicable.

### **EU - Plant Protection Products (1107/2009/EC)**

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE 7647-14-5	Plant protection agent

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## Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

## 15.2. Chemical safety assessment

Chemical Safety Report No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

### Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H301 - Toxic if swallowed. H361d - Suspected of damaging the unborn child. H314 - Causes severe skin burns and eye damage.  
H331 - Toxic if inhaled.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

**Revision date** 16-Jun-2025

**Prepared By** Pfizer Global Environment, Health, and Safety

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